K050048

510(k) Summary of Safety and Effectiveness for the Hoffmann® II Micro™ External Fixation System Line Extension

Proprietary Name:	Hoffmann® II Micro™ External Fixation System
Common Name:	External Fixation Frame Components
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030 and Smooth or threaded metallic bone fixation fastener, 21 CFR §888.3040
Device Product Code:	87 KTT, 87 LXT & 87 JEC
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	January 7, 2004

Intended Use:
The Hoffmann ® II Micro™ External Fixation System is intended for use to provide stabilization of open and/or unstable fractures in children and adults where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting or other means of internal fixation and for use in reconstruction procedures in conjunction with commercially available Fixation Pins and/or Kirschner Wires.

Description:
This line extension is to add new components to the Hoffmann ® II Micro™ External Fixation System. This component is an external fixation frame component and can be used with the components in other Howmedica Osteonics' external fixation systems such as the Hoffmann® II Micro™ External Fixation System, Hoffmann® II External Fixation System, Hoffmann® II Compact™ External Fixation System, Hoffmann® II Hybrid Frame System, Monotube Triax™ External Fixation System.

Substantial Equivalence:
Equivalency is based on similarities in intended use, materials and design to the predicate devices and the mechanical performance demonstrating substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

Ms. Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K050048
Trade/Device Name: Hoffmann® II Micro™ External Fixation System
Regulation Numbers: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: KTT
Dated: January 7, 2005
Received: January 10, 2005

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

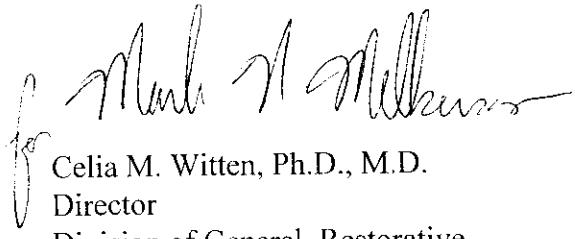
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Hoffmann® II Micro™ External Fixation System

Indications for Use:

The Hoffmann ® II Micro™ External Fixation System is intended for use to provide stabilization of open and/or unstable fractures in children and adults where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting or other means of internal fixation and for use in reconstruction procedures in conjunction with commercially available Fixation Pins and/or Kirschner Wires. Specific indications include, but are not limited to:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Non-unions and delayed unions
- Compression/distraction and lengthening

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050048